K061775

510(k) Summary

FEB 23 2007

Submitter's Name/Address
Wako Chemicals USA, Inc
Wako Diagnostics
1600 Bellwood Road
Richmond, Va. 23237

Contact Person:
Lori Creasy
Regulatory Affairs Specialist
804-714-1932
Fax: 804-271-0449

Date of Preparation of this Summary: December 28, 2006

Device Trade or Proprietary Name: L-Type Creatinine M

Device Common/Usual Name or Classification Name: Creatinine Test System

Classification Number/Class: Class II 862.1225

Product Code: JFY

Predicate Device: Creatinine HA

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K061775

Test Description:
Creatinine is an in vitro diagnostic assay for the quantitative determination of creatinine in serum, plasma or urine. Creatinine is produced directly from creatinine phosphate or by the dehydration of creatine in the muscles and nerves. The amount of metabolically produced creatinine in the urine is conveniently used to test glomerular function. Therefore, creatinine measurement is one of the essential clinical tests in the diagnosis of uremia and renal diseases such as renal insufficiency and nephritis, and in monitoring renal diseases. The enzymatic methods with high specificity are widely used to measure creatinine. L-Type Creatinine M is a reagent kit for creatinine assay based on the enzymatic method employing creatininase, creatinase, sarcosine oxidase and N-(3-sulfopropyl)-3-methoxy-5-methylaniline (HMMPS) as a new color agent.

Substantial Equivalence:
The L-Type Creatinine M is substantially equivalent to the Wako Creatinine HA 510(k) #K842847. Both assays yield similar Performance Characteristics.

Similarities:

- Both assays can be used for the quantitative of creatinine.
- Both assays yield similar results.

Differences:

Wako Creatinine HA 510 (k) # K842847	**Wako L-Type Creatinine M**
Jaffé Method, rate assay	HMMPS-method, end point assay
Determination of Serum and urine	Determination of Serum, Plasma and Urine.
Linearity = 0-25 mg/dL	Linearity Serum/Plasma 0.2-100 mg/dL Urine 1.0-200 mg/dL
LLD = 0.0 mg/dL	LLD Serum/Plasma= 0.03 mg/dL Urine = 0.06 mg/dL
Calibrator= Creatinine Standard Solution	Calibrator = Creatinine Calibrator

Intended Use:
L-Type Creatinine M is an in vitro diagnostic assay for the quantitative determination of creatinine in serum, plasma or urine.

Indications for use:
Creatinine measurement is one of the essential clinical tests in the diagnosis of uremia and renal diseases such as renal insufficiency and nephritis, and in monitoring renal diseases.

Performance Characteristics:
A comparison of the L-Type Creatinine M and a similar Creatinine HA (modified Jaffé method) was performed using a Hitachi 917. The test results provided the following data:
A correlation coefficient of 0.999, slope of 1.049 and a Y-intercept of –0.35 mg/dL for the serum application and a correlation coefficient of 0.998, slope of 1.038 and a Y-intercept of –0.94 for the urine application. A direct comparison between serum and plasma samples, both run on the L-type Creatinine M method, yielded a correlation coefficient of 0.999, slope of 1.002 and a Y-intercept of -0.04 for the serum/plasma application.

Precision Studies
Precision studies were conducted using the L-Type Creatinine M assay on the Hitachi 917.

Within-run precision:
The within-run precision: n=21 using 3 levels of controls. The within-run % CV ranged from 0.42 to 2.38 for serum/plasma and from 0.41 to 0.68 for urine.

Total precision:
Total precision data was collected according to CLIS EP5-A1 guideline over a period of 21 days. The total % CV ranged from 0.40 to 1.59 for serum/plasma and from 0.37 to 0.50 for urine.

Measurement of creatinine in serum and plasma is linear in the range from 0.2 mg/dL to 100 mg/dL. Measurement of creatinine in urine is linear in the range from 1.0 mg/dL to 200 mg/dL. If the creatinine value exceeds the upper limit of measurable range, dilute the sample with saline, repeat the assay, and multiply the result by the dilution factor.

Conclusion:
These data demonstrate that the performance of the L-Type Creatinine M assay is substantially equivalent to the Wako Creatinine HA assay on the Hitachi 917.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Lori Creasy
Regulatory Affairs Specialist
Wako Chemicals USA, Inc.
Wako Diagnostics
1600 Bellwood Road
Richmond, VA 23237

FEB 23 2007

Re: k061775
Trade/Device Name: L-Type Creatinine M
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY, JIT
Dated: January 09, 2007
Received: January 10, 2007

Dear Ms. Creasy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061775

Device Name: L-Type Creatinine-M

Indications For Use:

The L-Type Creatinine-M is an in-vitro assay for the quantitative determination of creatinine in serum, plasma, and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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